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RADIOLUCENT ECG ELECTRODE SYSTEM**BACKGROUND****1. Technical Field**

The present disclosure relates to biomedical electrodes, and in particular, to a radiolucent biomedical electrode connector and radiolucent lead wires for performing biomedical monitoring of a patient during imaging procedures.

2. Background of Related Art

Electrocardiograph (ECG) monitors are widely used to obtain medical (i.e., biopotential) signals containing information indicative of the electrical activity associated with the heart and pulmonary system. To obtain medical signals, ECG electrodes are applied to the skin of a patient in various locations. The electrodes, after being positioned on the patient, connect to an ECG monitor by a set of ECG lead wires. The distal end of the ECG lead wire, or portion closest to the patient, may include a connector which is adapted to operably connect to the electrode to receive medical signals from the body. The proximal end of the ECG lead set is operably coupled to the ECG monitor either directly or indirectly through an adapter, and supplies the medical signals received from the body to the ECG monitor.

A typical ECG electrode assembly may include an electrically conductive layer and a backing layer, the assembly having a patient contact side and a connector side. The contact side of the electrode pad may include biocompatible conductive gel or adhesive for affixing the electrode to a patient's body for facilitating an appropriate electrical connection between a patient's body and the electrode assembly. The connector side of the pad may incorporate a metallic press stud having a bulbous profile for coupling the electrode pad to the ECG lead wire. In use, the clinician removes a protective covering from the electrode side to expose the gel or adhesive, affixes the electrode pad to the patient's body, and attaches the appropriate ECG lead wire connector to the press stud by pressing or "snapping" the lead wire connector onto the bulbous press stud to achieve mechanical and electrical coupling of the electrode and lead wire. Alternatively, ECG connectors that engage via manipulation of a lever or other mechanical locking device may be employed. After use, a clinician then removes the ECG lead wire connector from the pad by pulling or "unsapping" the connector from the pad or by releasing the lever or other locking mechanism.

Placement of the electrodes on a patient has been established by medical protocols. A common protocol requires the placement of the electrodes in a 5-lead configuration: one electrode adjacent each clavicle bone on the upper chest and a third electrode adjacent the patient's lower left abdomen, a fourth electrode adjacent the sternum, and a fifth electrode on the patient's lower right abdomen.

During certain procedures it may be necessary to monitor biological (e.g., ECG) parameters of a patient that is undergoing imaging, such as CT-scan or MRI. Use of conventional ECG connectors and lead wire sets typically associated therewith may have drawbacks in these applications, since they tend to interfere with the imaging systems. In one example, certain components of the ECG connectors and/or lead wires may be detected by the imaging apparatus and consequently may obfuscate the visual images upon which clinicians and surgeons rely. In another example, ferrous and/or magnetic components commonly found in ECG connectors, such as in springs and clips, may be potentially hazardous when used within the intense magnetic field of an MRI scanner.

SUMMARY

In an embodiment in accordance with the present disclosure, there is provided an ECG lead system that, in accordance with embodiments of the present disclosure, comprises

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a radiolucent ECG lead set assembly and an ECG lead extension assembly. The ECG lead set assembly comprises a radiolucent ECG lead set cable having at least one radiolucent conductor. At least one radiolucent electrode connector is operatively coupled to a distal end of the ECG lead set cable, and an ECG intermediate lead set connector is disposed at a proximal end of the ECG lead set cable. The ECG lead extension assembly comprises an ECG lead extension cable having at least one conductor. An ECG lead set extension connector is disposed at a distal end of the ECG lead extension cable, and a device connector is disposed at a proximal end of the ECG lead extension cable. The ECG intermediate lead set connector is configured to operatively couple to the ECG lead set extension connector. The device connector is configured to operatively couple to an ECG monitor.

A method of performing an ECG on a patient undergoing an imaging procedure is provided. In embodiments according to the present disclosure, the method comprises providing one or more radiolucent ECG connectors as described herein, providing a radiolucent ECG lead system as described herein, attaching one or more electrode pads to the body of a patient, operatively coupling the one or more radiolucent ECG connectors to a corresponding one of the one or more electrode pads, operatively coupling the device connector to an ECG monitor, and imaging the patient in an imaging apparatus selected from the group consisting of an MRI scanner, a CT scanner, and a PET scanner. The method may include coupling the ECG intermediate lead set connector to the ECG lead set extension connector. Additionally or alternatively, the method may include providing an adapter configured to enable operable coupling of the device connector to an ECG monitor, coupling the device connector to the adapter, and coupling the adapter to the ECG monitor.

In another aspect, an ECG connector assembly in accordance with the present disclosure includes a housing having an opening defined therein configured to operably receive an electrode post of an ECG electrode pad. The ECG connector assembly includes an electrode member having a generally semicircular contact face and is disposed along at least a part of the perimeter of the opening. The ECG connector assembly includes an engagement member having an actuation surface and an engaging face. The engagement member is pivotable about a pivot to enable the engaging face to move from a first position whereby the engaging face is closer to the contact face and a second position whereby the engaging face is further from the contact face. A resilient radiused member joins a finger to a proximal end of the engagement member and is configured to bias the engagement member towards the first position. The ECG connector assembly includes a leadwire configured to operatively couple the electrode member to an ECG monitor.

In some embodiments, at least one of the electrode member or the leadwire is formed from radiolucent material. In some embodiments, the electrode member includes a junction block configured to facilitate operational coupling with the leadwire conductor. In some embodiments, the housing includes a retaining rib defining a cavity configured to retain the electrode member to the housing. In some embodiments, the actuating surface may include one or more ergonomic features, such as without limitation one or more scallops, one or more ridges, one or more grooves, knurling, contouring, a friction-enhancing surface, an elastomeric coating, an elastomeric grip, or a textured grip. In some embodiments, the ECG connector includes a bulkhead provided by the housing wherein the finger slidably engages the bulkhead when the engagement member moves between the first position and the